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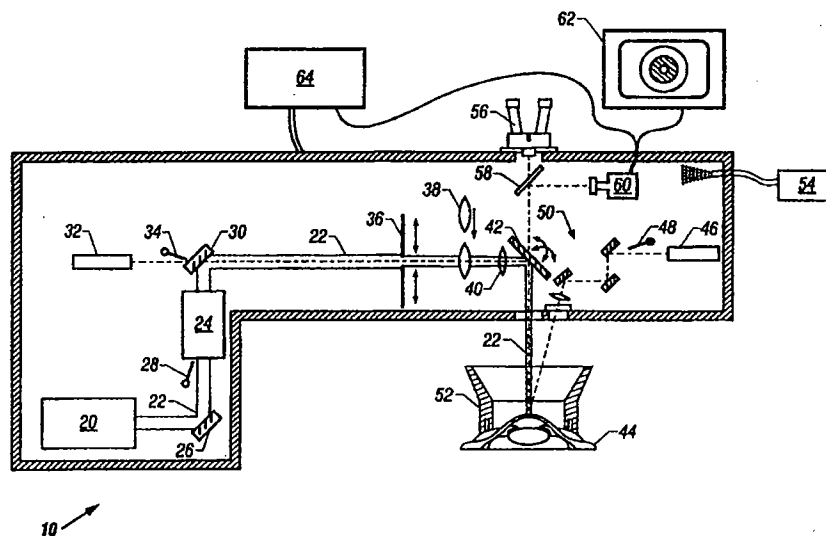
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(54) Title: DUAL MODE OPHTHALMIC LASER ABLATION



(57) Abstract

A dual mode excimer laser eye surgery system is provided. The eye is first treated for primary corneal defects using a large, fixed spot size, and remaining irregularities are removed using a small fixed spot size. The large size allows for faster treatment, and the small size provided for more precision in the treatment of irregular topographies. The system is preferably implemented in a distributed topography environment. For example, a treatment pattern using a large, fixed spot size is provided to doctors based on visual acuity data, such as the degree of dioptric correction needed. The effect of this treatment is then overlaid on a computer against the patient's actual eye topography. The small fixed spot size is used to remove any remaining irregularities yielding a preferred treatment pattern. This combined treatment pattern is then distributed to an excimer laser eye surgery system that performs the large spot size ablation and then the small spot size ablation.

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DUAL MODE OPHTHALMIC LASER ABLATION

The invention relates to an apparatus and technique for surgically modifying the
5 curvature of the eye cornea and a method of controlling the apparatus, and more
particularly to an apparatus for immediately correcting a variety of corneal defects using
dual, fixed spot sizes.

Excimer laser eye surgery systems are often used for correcting vision. From eye
glasses to radial keratotomy, ophthalmic surgery has now progressed to a point where the
10 surface of the eye is actually reshaped using cold light laser ablation provided by excimer
lasers, typically argon fluoride lasers operating at around 193 nanometers. These lasers
are even used to reshape the stromal tissue underneath the surface of the eye in a laser *in
situ* keratomileusis technique patented by Gholam Peyman in U.S. Patent No. 4,840,175.

These techniques start with the uncorrected profile of the eye, and then ablate the
15 eye using various small or large beam techniques, or aperture techniques, to reprofile the
surface into a desired, corrected profile. The amount of correction is determined by a
variety of methods, but for myopia, for example, given the starting curvature of the eye
and the amount of dioptric correction needed, equations are well known which specify the
amount of tissue that must be removed from each point on the surface of the eye. These
20 equations are found, for example, in PCT Patent Application Serial No. PCT/EP93/02667.
Similar equations are known for the amount of tissue necessary for removal to correct
for hyperopia and astigmatism.

Before relying on these equations, however, the actual curvature of the eye must
be determined. This is done using a number of techniques. The patient's visual acuity can
25 be determined through eye exams. The actual shape of the surface of the eye can be
determined, for example, using a topography system. These topography systems can be
either manual or computerized, and the latter can provide a point-by-point representation
of the curvature of the eye, for example, in the form of an axial curvature, the
instantaneous or true local curvature, or the absolute height.

Typically, based on these curvatures and a patient's visual acuity, a doctor programs into an excimer laser surgery system an amount of positive or negative dioptric correction (depending on whether the correction is for hyperopia or myopia) and an angle of the cylinder of astigmatism, if any, along with the amount of dioptric correction
5 necessary for the astigmatism. Software within the excimer system itself then calculates a shot pattern suitable for achieving the objective, and that pattern is executed on the surface of the patient's eye.

International Publication No. WO 97/46183 (International Application No. PCT/EP97/02721) discloses a distributed system for controlling excimer laser surgery.
10 A topography system, a computer system, and an excimer laser eye surgery system are provided, with the topography system providing profile data to the computer system, and the computer system calculating and providing an ablation shot pattern to the excimer laser eye surgery system. The computer system and the excimer laser eye surgery system can be located remotely. The excimer laser eye surgery system can receive data from
15 more than one computer system and from more than one topography system for better utilization of resources.

A number of systems have been developed to reshape the cornea, using a variety of techniques such as variable sized circular apertures to correct for myopia, variable sized ring shaped apertures to correct for hyperopia, and variable sized slit shaped apertures
20 correct for astigmatism. These techniques collectively came to be known as photorefractive keratectomy. It has been recognized that using such apertures to correct for myopia, for example, a series of excimer laser shots using progressively smaller spot sizes could ablate away a portion of the cornea to effectively build a "corrective lens" into the cornea.

25 These techniques are discussed, for example, in U.S. Patent No. 4,973,330, entitled "Surgical Apparatus for Modifying the Curvature of the Eye Cornea," issued November 27, 1990, and in U.S. Patent No. 4,729,372, entitled "Apparatus for Performing Ophthalmic Laser Surgery," issued March 8, 1988. Those skilled in the art of laser ophthalmological surgery have extensively developed the required exposure
30 patterns using these variable size apertures to provide an appropriate amount of correction

to various degrees of myopia, hyperopia, and astigmatism, and a combination of these conditions. These multiple aperture systems tend to be complicated and inflexible. A number of aperture wheels or masks are required, and only standard forms of correction for myopia and hyperopia with circular symmetry and astigmatism with cylindrical symmetry are provided.

An apparatus for ablating tissue from the eye is shown in U.S. Patent No. 4,973,330, referenced above. This apparatus includes an excimer laser, the laser beam of which impinges on the cornea, with the axis of the laser beam coinciding with the optical axis of the eye. Furthermore, a field stop limits the area of the laser spot on the cornea illuminated by the laser beam, and the size of this field stop is set in a temporarily variable manner according to the profile of the area to be removed so that the thickness of the area to be removed is a function of the distance from the optical axis of the eye.

The system described in U.S. Patent No. 4,973,330 permits in this way setting the "laser energy deposited" on the cornea as the function of the distance from the optical axis of the eye, but only under the condition that the distribution of energy (i.e., the power of the laser beam spot) is homogeneous, or at least axially symmetrical. This, however, is a condition that excimer lasers in particular do not always fulfill. Inhomogeneous power distribution results in non-axially symmetrical removal. Moreover, the system described in U.S. Patent No. 4,973,330 only permits the correction of spherical aberrations, not astigmatism.

An apparatus based on the same fundamental idea is known from U.S. Patent No. 4,994,058, entitled "Surface Shaping Using Lasers", issued February 19, 1991. That apparatus employs a "destructible field stop mask" instead of a field stop having a temporarily variable aperture.

Another class of apparatus for shaping the cornea by means of removing tissue is known from the various L'Esperance patents. These include U.S. Patent Nos. 4,665,913; 4,669,466; 4,718,418; 4,721,379; 4,729,372; 4,732,148; 4,770,172; 4,773,414; and 4,798,204. In that apparatus, a laser beam with a small focus spot is moved by a two-dimensional scanning system over the area to be removed. This apparatus, which operates

as a "scanner," has the advantage that it can generate any two-dimensional profile of deposited energy "over the area to be removed."

International Publication No. WO 96/11655 (International Application No. PCT/EP95/04028) discloses an apparatus and method for controlling an apparatus for removing tissue from the eye, performing various types of corrections using a relatively large beam, but oscillating or dithering to prevent reinforcing ridges from being formed during the tissue removal process. Various types of correction, such as hyperopia and astigmatism correction, are performed using a large beam that is scanned over the area to be ablated using overlapping shots.

Using an infrared fluorescent dye to dye the epithelium, the epithelium in the area to be treated is removed while observing the fluorescent patterns from the epithelium. Once a certain area is no longer fluorescent after laser shots, smaller shots are then applied, selectively removing the epithelium from the remaining regions. Using two astigmatism correcting ablation patterns intersecting at an angle, a lens is created capable of correcting for myopia, hyperopia, and astigmatism. Overlapping shots, using a relatively large fixed spot size, provide for reduced thermal heating, ridgeless treatment patterns, reduced shot count and simplified equipment. Thus, this reference illustrates a single fixed spot size system using a large fixed spot in an overlapping pattern to correct vision.

With the various advances, excimer laser eye surgery systems implement a variety of techniques to re-profile the surface of the eye. The use of large spot sizes reduces treatment time and increases the amount of tissue removed per shot, but small spot sizes provide for finer resolution of correction. A technique and apparatus with the advantages of both would be greatly desirable.

According to the invention, a dual mode excimer laser eye surgery system is provided. In this system, the eye is first treated for primary corneal defects, such as myopia, hyperopia, and astigmatism, using a large, fixed spot size. Then, a small fixed spot size is used to remove remaining irregularities. The large size allows for faster treatment. The small size provides for more precision in the treatment of irregular topographies.

Further, such a system is preferably implemented in a distributed topography environment. For example, a treatment pattern using the large, fixed spot size is provided to doctors based on visual acuity data, such as the degree of dioptric correction needed.

Then, the effect of this treatment is overlaid on a computer against the patient's actual
5 eye topography. The doctor then uses the small fixed spot size to remove any remaining irregularities yielding a preferred treatment pattern. This combined treatment pattern is then distributed to an excimer laser eye surgery system that performs the large spot size ablation and then the small spot size ablation.

Fig. 1 is a simplified diagram illustrating a typical excimer laser eye surgery
10 system.

Fig. 1A illustrates a dual fixed diaphragm that would replace the variable diaphragm in the excimer laser eye surgery system of Fig. 1, wherein a large spot size diaphragm opening is positioned in the path of a laser beam, according to the present invention.

15 Fig. 1B illustrates the dual fixed diaphragm of Fig. 1A, wherein a small spot size diaphragm opening is positioned in the path of the laser beam, according to the present invention.

Fig. 2 is an illustration of portion of a first pass for correcting vision using the large fixed spot size.

20 Fig. 2A is an illustration of a typical shot pattern.

Fig. 3 is an illustration of the second pass for correcting vision using a smaller fixed spot size.

Fig. 4 is a block diagram illustrating the interrelationship of multiple components in an excimer laser eye surgery system.

25 Fig. 1 shows a typical eye surgery system 10. An excimer laser 20 provides a pulsed beam 22 to a beam homogenizer 24 after reflection from optics 26. A shutter 28 is also provided to block transmission of the pulsed beam 22 to the beam homogenizer 24.

The excimer laser 20 is a typical excimer laser as is well known in the art. It preferably provides a 193 nm wavelength beam with a maximum pulse energy of 400 mJ/pulse. The
30 excimer laser 20 preferably provides maximum power at the treatment site of 1 W, with

a pulse frequency of 10 Hz and a pulse length of 18 ns. By way of example, the wavelength of the light from the laser is preferably less than 400 nm, as that provides the desired ablating action with reduced thermal heating. Further, other pulse energies can be provided, such as all the way down to 200 mJ/pulse, with typical repetition rates of 60
5 to 100 pulses per second with a typical pulse length of 10 to 30 ns.

The beam homogenizer 24 preferably includes standard homogenization and focusing hardware, which can be based both on optical mixing of the beam and on rotation of the beam. From the beam homogenizer 24, the pulsed beam 22 is then reflected off of optics 30, which also passes a red pilot laser beam from a pilot laser 32. This pilot laser
10 32 is preferably a 633 nm helium neon laser of less than 1 mW of power. The red pilot beam from the pilot laser 32 can also be blocked by a shutter 34. The pilot laser 32 is aligned so that its optical pathway coincides with the pulsed beam 22. The pilot laser 32 provides the functions of centering the beam 22 on the axis of treatment of the eye 44 and also provides for focusing on the eye 44. Further, it can provide an optical fixation point
15 for the patient, although a different laser or light source could also be provided for that purpose.

From the optics 30, the pulsed beam 20 (now also co-aligned with the beam from the pilot laser 32) then passes through an adjustable diaphragm 36, which allows the beam size to be adjusted before it enters the final optics. After the diaphragm 36, a spot mode
20 lens 38, when in place, provides further concentration of the beam 22, allowing spot ablation of certain defects in the eye by a physician performing therapeutic rather than refractive surgery. The spot mode lens 38 is thus moved into and out of place depending on whether therapeutic or refractive treatment is desired.

Following the spot mode lens 38, a focusing lens 40 directs the beam 22 onto the
25 scanning mirror 42, which then reflects the beam 22 onto a patient's eye 44. Note that the portion of the beam 22 from the pilot laser 32 is used for both adjusting the distance of the eye 44 from the entire eye surgery system 10 and for providing centering, as will be discussed below. The focusing lens 40 focuses light such that when the eye 44 is at the optimal distance, the beam 22 is properly focused onto the eye 44.

These various lenses and mirrors thus combine to form an optical system providing an excimer beam to the cornea. The optical system creates a laser spot on the cornea, and the spot size is adjustable, along with its location. It will be readily appreciated that a wide variety of different systems could be used to optically provide such a beam. For example, a lens could be used to adjust the spot size rather than an aperture, and instead of a scanning mirror, the patient or the patient's eye 44 could be physically moved to provide for shots at different locations on the eye 44.

Also provided in the system is a focusing laser 46, whose beam can also be blocked by a shutter 48. The focusing laser 46 is preferably a green helium neon laser providing a beam of a wavelength of 535 nm and less than 1 mW of power. The beam from the focusing laser 46 travels through optics 50 and impinges on the eye 44 at an angle. The distance of the eye 44 from the eye surgery system 10 is adjusted such that both the beam from the pilot laser 32 and the beam from the focusing laser 46 impinge on the surface of the eye 44 at the same point.

Further provided is an optional fixation mask 52, which is well known in the art and is used to stabilize the eye 44 during surgery. It can include debris removal components, and is typically attached to the eye 44 through either a vacuum suction ring or through hooks. A clean gas purge unit 54 ensures that the optics and the beams in the system are free from any floating debris.

A microscope 56 is provided for the physician to observe progress during ablation of the surface of the eye 44. The microscope 56 is preferably a ZEISS OPMI "PLUS" part No. 3033119910, with magnifications of 3.4, 5.6 and 9.0 times. Field illumination is provided by a cold light source not shown, which is preferably the Schott KL1500 Electronic, ZEISS part number 417075. This microscope 56 focuses through the scanning mirror 42 and also focuses through a splitting mirror 58. The splitting mirror further provides a view of the eye 44 to an infrared video unit 60, which is used for the epithelial ablation discussed below. The infrared video unit 60 preferably provides an image output to a capturing video screen 62 and to a control unit 64. The infrared video unit 60 is preferably sensitive to both infrared light and visible light.

The control unit 64, which is typically a high performance computer compatible with an IBM PC by International Business Machines Corp., further preferably controls all components of the eye surgery system 10, including the shutters 28, 34, and 48, the diaphragm 36, the spot mode lens 38, and the scanning mirror 42.

5 With reference to Figs. 1A and 1B, a typical dual diaphragm is illustrated that would be used according to the invention to implement dual fixed spot size excimer laser surgery. According to the invention, for example, one would replace the variable diaphragm 36 (Fig. 1) with the dual fixed diaphragm illustrated in Figs. 1A and 1B. Specifically, a dual diaphragm plate 1000 is slidable to the left or to the right. It is placed
10 in a path of laser beam 22 (Fig. 1) and shifted between its two positions to provide two different spot sizes of the beam. In Fig. 1A, the diaphragm plate 1000 is in a first position in which a large spot sized diaphragm opening 1002 is positioned in the path of the laser beam 22. As is seen, this large diaphragm opening 1002 passes a circular beam 1004 of a first size. A remainder 1006 of the beam 22 is reflected into a laser dump 1008 where
15 it is absorbed.

When it is desired to employ the second, smaller spot size, as illustrated in Fig. 1B, the diaphragm plate 1000 is shifted into a second position. In this position, a smaller diaphragm opening 1010 passes a smaller laser spot 1012. Again, a remainder 1014 of the beam 22 is reflected into the laser dump 1008.

20 It will be appreciated that the actual size of the spots of the diaphragm openings 1002 and 1010 will not necessarily exactly coincide with the size of a spot that alights on the eye 44. However, it will be appreciated that these two spot sizes will provide for two different sizes of beam impingement on the eye 44. Preferably, the diaphragm opening 1002 is of a size to form an approximately two millimeter diameter spot size on the eye,
25 whereas the opening 1010 is of a size appropriate to form a one millimeter diameter spot size. Other sizes can be used, preferably with the first size large enough to fairly quickly perform a basic ablation pattern, with the second size being relatively small, small enough to provide precise correction of any remaining defects.

Turning to Figure 2, illustrated is a typical first pass on a 6 millimeter treatment
30 zone using a 2 millimeter spot on the eye formed by the first diaphragm opening 1002.

This is illustrative only, and preferably would be a pattern such as that illustrated in Fig. 2A. For additional patterns and methods of operation, see International Publication No. WO 96/11655 (International Application No. PCT/EP95/04028), particularly Figs. 19-28 and the related discussion. Using a large, 2 millimeter spot, a basic ablation profile is
5 achieved.

Then turning to Figure 3, assume that after the basic ablation performed in Figure 2, a remaining area 1020 is irregular compared to a desired eye profile. Then, the smaller spot formed by the opening 1010 is used to create a plurality of shots 1022 that "smooth" the remaining irregularity.

10 Preferably, the dual spot size system according to the invention is used in conjunction with a topography system. With reference to Fig. 4, for example, a topography system T1 is used in conjunction with other visual acuity techniques to determine the degree and type of correction a patient needs, such as for myopia, hyperopia, or astigmatism. A basic treatment pattern is developed by a computer C1
15 based on the topographic data provided by the topography system T1 and implemented on an excimer laser eye surgery system E1. Second and third topography systems T2 and T3, respectively, are coupled to a computer system C2, which is coupled to an excimer laser eye surgery system E2 and also to eye surgery system E1. Computer C1 is also coupled to eye surgery system E2, and all of these components together provide a
20 distributed topography, treatment creation and excimer laser system. See International Publication No. WO 97/46183 (International Application No. PCT/EP97/02721) for more information on distributed excimer laser surgery systems.

The basic treatment pattern, however, may need refinement because of irregularities in the profile of the patient's eye. Therefore, the doctor could compare the
25 calculated results of the basic treatment pattern using the large spot size with the desired topography. Then, simulating the use of the smaller spot size, the doctor could use free hand techniques to provide appropriate shots within the treatment pattern to correct for the remaining irregularity, resulting, for example, in the treatment of Figure 3. This detailed correction could either be provided with computer assistance suggesting a
30 sequence of smaller shots to fill in the irregular area, or perhaps using a cursor, mouse,

or other pointing device to allow the doctor to "paint" in the area to be treated. The computer system would then calculate the theoretical result of ablating an eye with the topography determined by the topography system T1, and hopefully this would be within an acceptable error limit. If not, the doctor could provide further refinements using the
5 smaller spot size.

Therefore, using the techniques according to the invention, a large, fixed spot size is used to provide for basic correction of hyperopia, myopia, or astigmatism. Then, any remaining irregularities are removed using the smaller fixed spot size. Further, the large spot size pattern can be automatically calculated, with the small spot size being manually
10 "painted in" by the physician, or could be automatically calculated under the physician's supervision.

It will be appreciated that a variety of techniques can be used to provide the two spot sizes. For example, instead of using the sliding dual diaphragm, a variable diaphragm as in the diaphragm 36 of Figure 1 could be used, but simply
15 programmed to only assume two different sizes. One skilled in the art will appreciate the variety of techniques to form two discrete sizes.

Preferably, the large fixed spot size uses a large, fixed spot size scanning technique, and the small fixed spot size is provided with small overlapping shots.

The foregoing disclosure and description of the invention are illustrative and
20 explanatory thereof, and various changes in the size, shape, materials, components, circuit elements, and optical components, as well as in the details of the illustrated system and construction and method of operation may be made without departing from the spirit of the invention.

CLAIMS:

- 1 1. An apparatus for shaping the cornea by removing tissue from a region of the
2 cornea that has an area to be subject to ablation to a desired treatment pattern, the
3 apparatus comprising:
4 a laser that emits a laser beam having a suitable wave length;
5 an optical system coupled to said laser that receives the laser beam and images the
6 laser beam onto the cornea;
7 dual spot optics coupled to the optical system for restricting the optical system to
8 provide the laser beam at a first large fixed spot size on the cornea and a second small
9 fixed spot size on the cornea, wherein the first large fixed spot size on the cornea is a
10 relatively large fraction of the area of the cornea to be subject to ablation, and the second
11 small fixed spot size on the cornea is relatively small compared to the large fixed spot size;
12 and
13 a controller for directing the optical system and for directing said laser to fire the
14 laser beam and the optical system to image the laser beam in a series of shots at the large
15 fixed spot size and small fixed spot size.
- 1 2. The apparatus of claim 1, wherein the dual spot optics includes a dual fixed
2 diaphragm.
- 1 3. The apparatus of claim 2, wherein the dual fixed diaphragm is placed in the
2 path of the laser beam.
- 1 4. The apparatus of claim 2, wherein the dual fixed diaphragm slides between
2 a first position and a second position.
- 1 5. The apparatus of claim 2, wherein the dual fixed diaphragm has a first
2 opening and a second opening smaller than the first opening.
- 1 6. The apparatus of claim 1, wherein the dual spot optics includes a dual fixed
2 diaphragm placed in the path of the laser beam, the dual fixed diaphragm sliding between
3 a first position and a second position and having a first opening and a second opening

smaller than the first opening, the laser beam passing through the first opening when the dual fixed diaphragm is in the first position and through the second opening when the dual fixed diaphragm is in the second position.

7. The apparatus of claim 1, wherein the dual spot optics includes a diaphragm that is adjustable.

8. A method for ablating tissue from an eye, comprising:
providing a laser eye surgery system having dual spot optics;
performing surgery on the eye with the dual spot optics in a first position for a first pass treatment to provide a basic ablation profile;
changing a position in the dual spot optics to a second position; and
performing surgery on the eye in a second pass treatment to remove irregularities.

9. The method of claim 8, wherein the dual spot optics has a dual diaphragm.

10. The method of claim 9, wherein the dual diaphragm includes a plate having two holes, wherein one hole is larger than the other hole.

11. The method of claim 10, wherein the step of changing the position in the dual spot optics includes sliding the plate.

12. The method of claim 10 or 11, including passing a laser beam through one of the two holes in the plate.

13. A method of treatment for an eye using a laser system, the laser system including a laser that emits a laser beam having a suitable wavelength and the laser system including an optical system that images the laser beam onto a cornea that has an area to be subject to ablation to a desired treatment pattern, the method comprising the steps of:

calculating a shot dithering pattern corresponding to an initial treatment pattern;

13

directing the laser system to provide a large fixed spot size laser beam on the cornea;

directing the laser system to fire the laser beam with a series of shots corresponding to the shot dithering pattern;

ablating the cornea with the large fixed spot size laser beam to achieve the initial treatment pattern;

adjusting the laser system to provide a small fixed spot size laser beam on the cornea, wherein the small fixed spot size laser beam is smaller in diameter than the large fixed spot size laser beam; and

ablating the cornea with the small fixed spot size laser beam to achieve the desired treatment pattern.

14. The method of claim 13, wherein the large fixed spot size laser beam has a diameter of at least 2.0 mm.

15. The method of claim 13 or 14, wherein the small fixed spot size laser beam has a diameter of not more than 1.0 mm.

16. The method of any of claims 13 to 15, further comprising the step of determining the initial treatment pattern based on visual acuity data.

17. The method of any of claims 13 to 16, further comprising the step of overlaying the effect of the initial treatment pattern on a patient's actual eye topography.

18. The method of claim 13, further comprising:
determining the initial treatment pattern based on visual acuity data using a topography system;
overlaying the effect of the initial treatment pattern on a patient's actual eye topography; and
transmitting the initial and the desired treatment patterns to the laser system, the laser system being in a different location than the topography system.

19. A laser surgery system for treating an eye, comprising:

a topography system that provides profile data corresponding to the profile of the cornea of a patient;

a computer system with a program for developing an initial ablation shot pattern from the profile data;

a first data link between said topography system and said computer system for transmission of the profile data from said topography system to said computer system;

a laser eye surgery apparatus for firing a large fixed spot size laser beam in a shot pattern corresponding to the initial ablation shot pattern;

a second data link between said computer system and said laser eye surgery apparatus for transmission of the initial ablation shot pattern from said computer system to said laser eye surgery apparatus, wherein said laser eye surgery apparatus is located in a physically different vicinity than said computer system; and

means for firing the laser eye surgery apparatus in a small fixed spot size laser beam to achieve a desired treatment plan, the small fixed spot size laser beam having a smaller diameter than the large fixed spot size laser beam.

20. The laser surgery system of claim 19, wherein the means for firing the laser eye surgery apparatus in a small fixed spot size laser beam includes a dual fixed diaphragm placed in the path of the laser beam, the dual fixed diaphragm sliding between a first position and a second position and having a first opening and a second opening smaller than the first opening.

21. The laser surgery system of claim 19 or 20, wherein the means for firing the laser eye surgery apparatus in a small fixed spot size laser beam includes an adjustable diaphragm for selecting a diameter for the laser beam.

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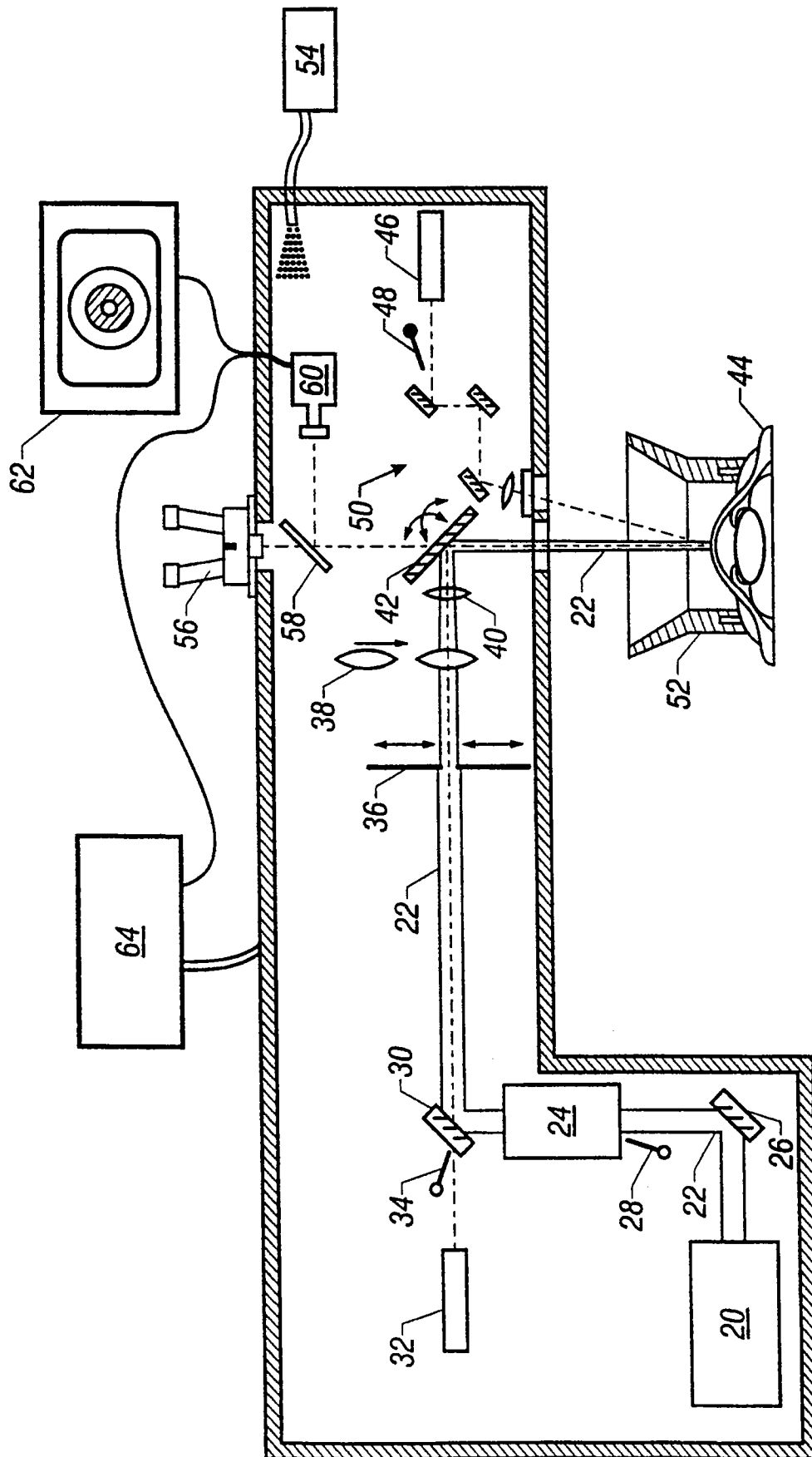


FIG. 1

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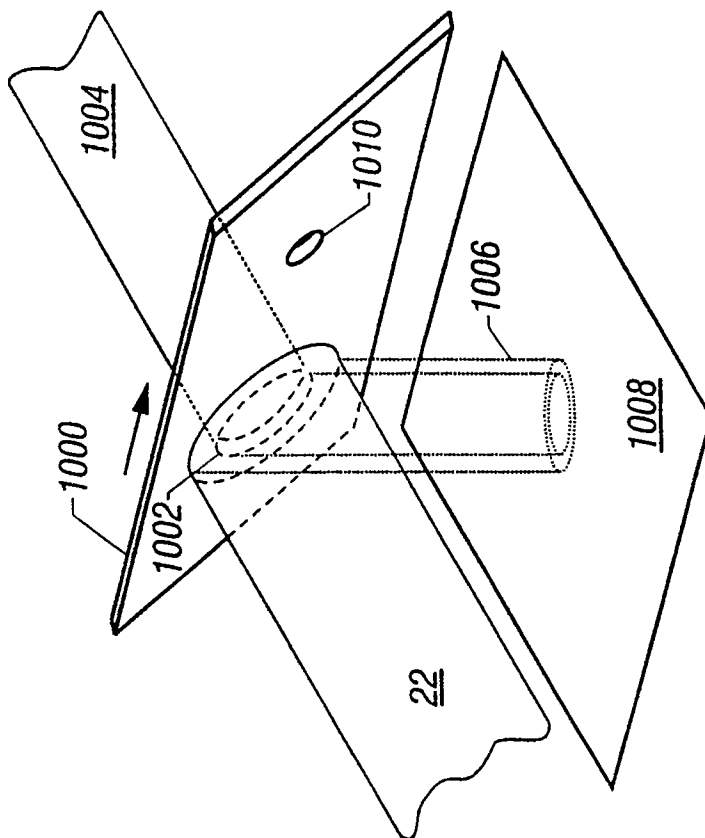


FIG. 1A

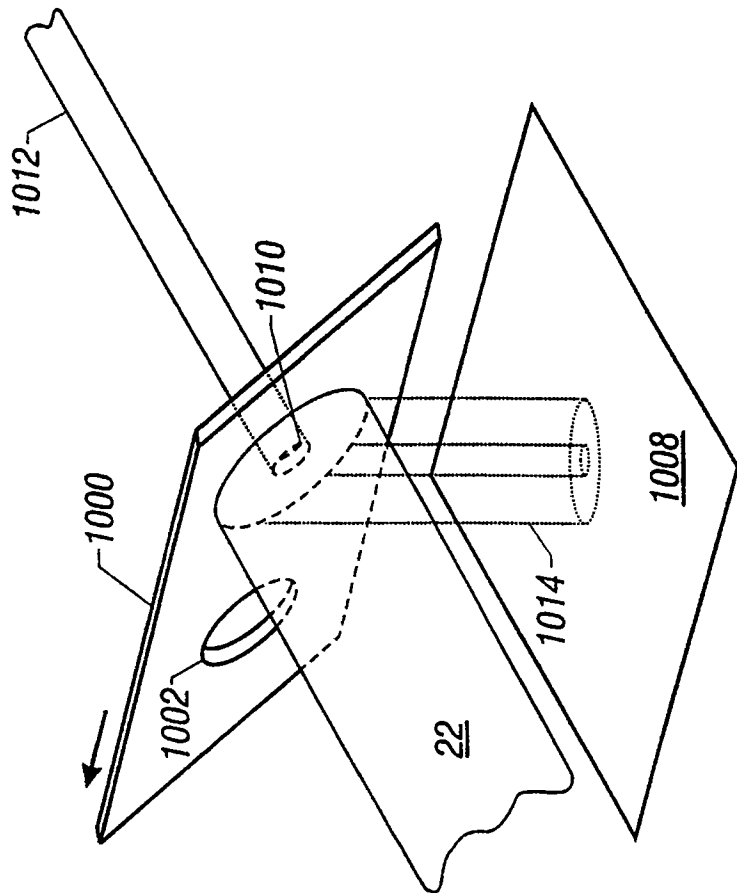


FIG. 1B

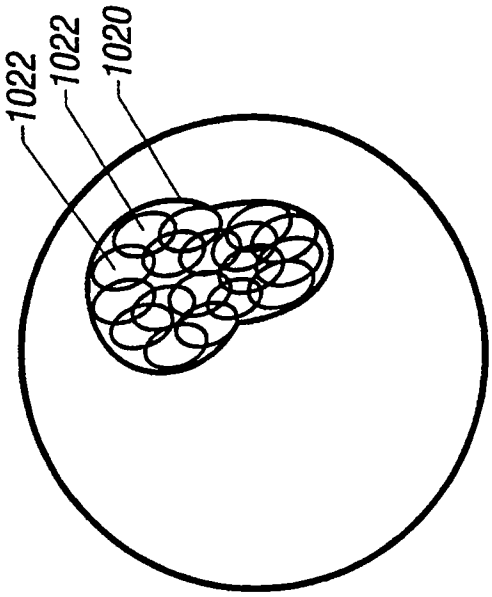


FIG. 3

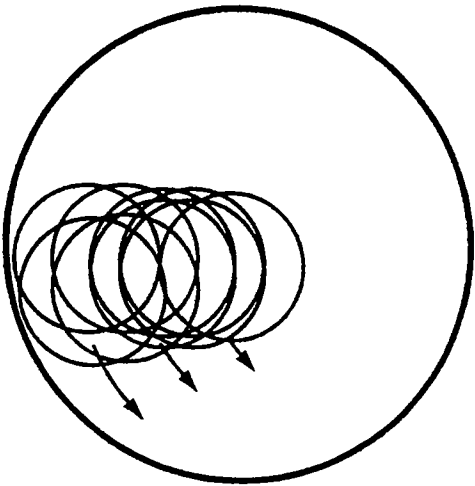


FIG. 2

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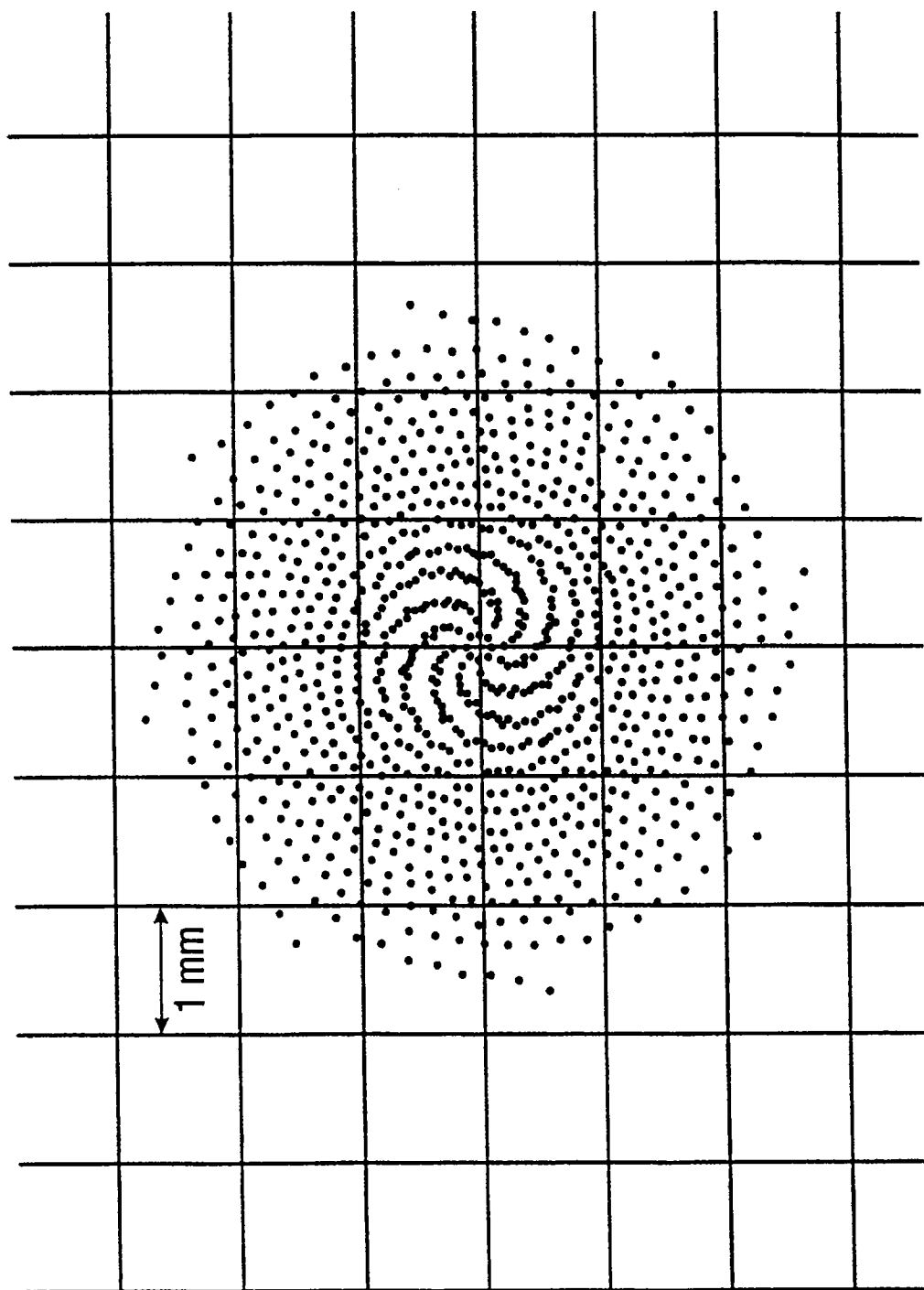


FIG. 2A

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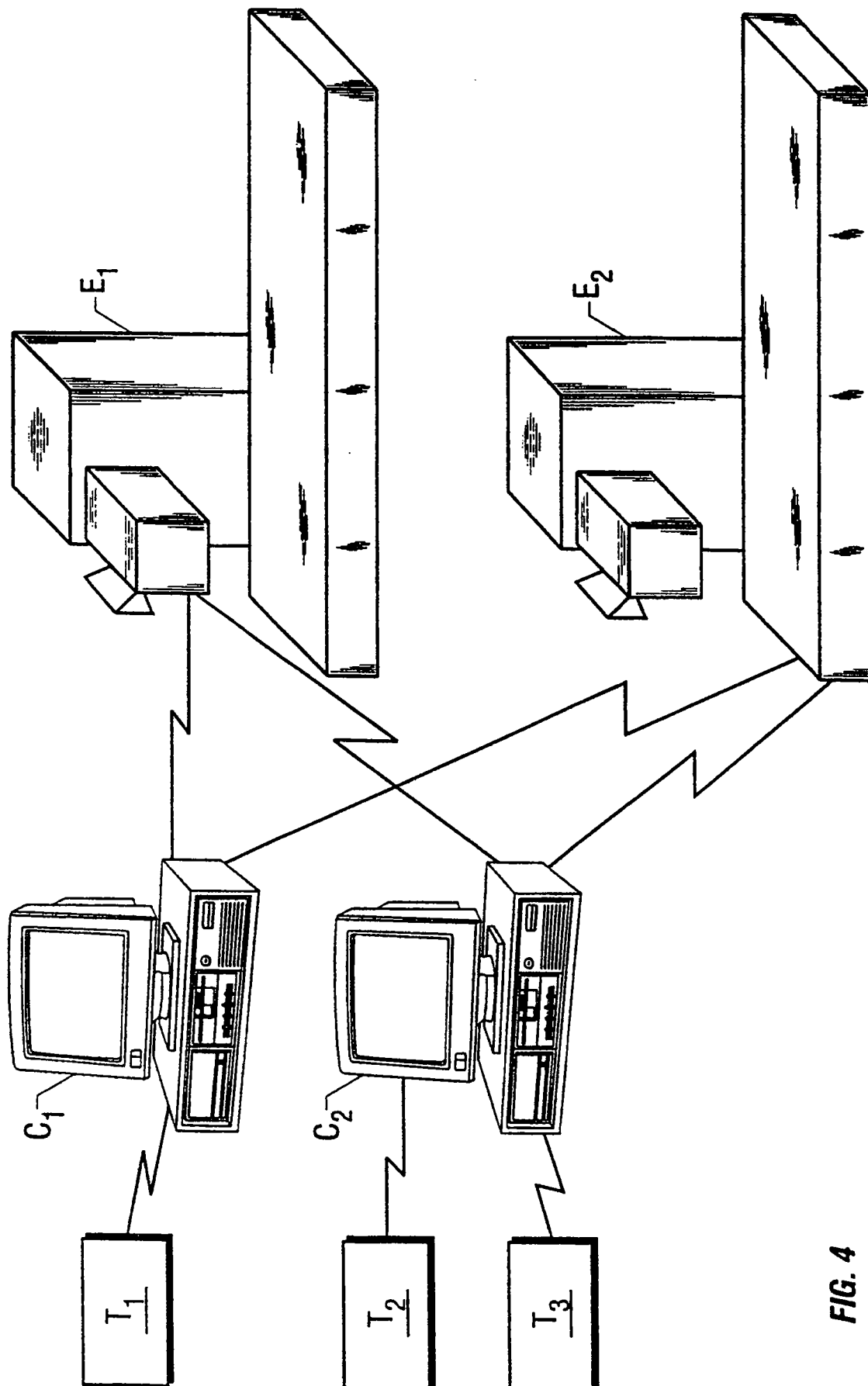


FIG. 4

A. CLASSIFICATION OF SUBJECT MATTER
IPC 6 A61F9/007

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 6 A61B A61F

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	WO 96 21407 A (SUMMIT TECHNOLOGY) 18 July 1996'	1-7
A	see page 9, line 5-10	19
Y	EP 0 412 789 A (SUMMIT TECHNOLOGY) 13 February 1991 see claims 1,4	1-7
A	DE 41 03 493 C (AESCULAP AG) 9 July 1992 see claim 1	1
A	WO 92 16141 A (WILK) 1 October 1992 see claim 1	19
A,P	WO 97 46183 A (HOHLA) 11 December 1997 see claim 16	19

☐ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

* Special categories of cited documents :

- *A* document defining the general state of the art which is not considered to be of particular relevance
- *E* earlier document but published on or after the international filing date
- *L* document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
- *O* document referring to an oral disclosure, use, exhibition or other means
- *P* document published prior to the international filing date but later than the priority date claimed

T later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

X document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

Y document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

G document member of the same patent family

Date of the actual completion of the international search

28 August 1998

Date of mailing of the international search report

03.09.98

Name and mailing address of the ISA

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Authorized officer

Glas, J

INTERNATIONAL SEARCH REPORT

International application No.
PCT/EP 98/02428

Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☒ Claims Nos.: 8-18
because they relate to subject matter not required to be searched by this Authority, namely:
Rule 39.1(iv) PCT - Method for treatment of the human or animal body by surgery
2. ☐ Claims Nos.:
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:
3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. ☐ As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:
4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest.
- ☐ No protest accompanied the payment of additional search fees.

Patent document cited in search report		Publication date	Patent family member(s)		Publication date
WO 9621407	A	18-07-1996	AU	4530696 A	31-07-1996

EP 412789	A	13-02-1991	AT	132357 T	15-01-1996
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